

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVMEBER 2008**

**CON REVIEW: MU-NIS-0908-037
ALLIANCE ONCOLOGY, LLC D/B/A BETHESDA REGIONAL
CANCER TREATMENT CENTER
ESTABLISHMENT AND PROVISION OF MOBILE POSITRON
EMISSION TOMOGRAPHY (PET) SERVICES
CAPITAL EXPENDITURE: \$67,000
LOCATION: CLARKSDALE, COAHOMA COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center (Bethesda) is a limited liability company established September 25, 2007. The application contains a copy of its certification of formation and a letter of good standing signed by the Mississippi Secretary of State. Bethesda is a freestanding health care facility operated by Alliance Oncology, LLC.

Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center currently offers outpatient radiotherapy and related services.

Alliance Oncology, LLC has four (4) directors and five (5) officers.

B. Project Description

Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center requests Certificate of Need (CON) authority to establish positron emission tomography (PET) services at Bethesda. Bethesda will contract with Alliance Imaging, Incorporated, Alabaster, Alabama, to provide mobile PET services. Bethesda Regional Cancer Treatment Center plans to lease, from Alliance Imaging, a General Electric Discover ST 4 PET/CT (unit #63) and a tractor and trailer to transport the equipment one day a week at Bethesda. The application contains a copy of the proposed services agreement between Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center and Alliance Imaging for the proposed project.

According to the applicant, Bethesda will create the concrete pad and electrical connections (capital improvement cost) necessary to accommodate the mobile PET/CT unit/services at Bethesda.

The total proposed capital expenditure is \$67,000 and of that amount, approximately 41.04 percent is for capital improvement; 1.49 percent for site preparation; 14.93 percent for fees (architectural, consultant, etc.); 29.86 percent for contingency

reserve; and 12.86 percent for other (legal and accounting fees and CON filing fee). The applicant proposes to finance the proposed capital expenditure from accumulated cash reserves.

According to the MSDH Division of Health Facilities Licensure and Certification, the proposed project's site is approved for immediate use.

According to the applicant, the anticipated date for obligation of the capital expenditure will be January 2009. The applicant proposes the completion date of the proposed project will be June 2009.

II. TYPE OF REVIEW REQUIRED

Projects which propose the provision of positron emission tomography (PET) services are reviewed in accordance with Section 41-7-191, subparagraphs (1) (d) (xv) Mississippi Code of 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197(2), of the Mississippi Code 1972, Annotated, as amended, any affected person may request a public hearing on this project within 20 days of publication of the staff analysis. The opportunity to request a hearing expires on December 4, 2008.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The *FY 2009 State Health Plan* addresses policy statements and service specific criteria and standards which an applicant is required to meet before receiving CON authority to provide PET services. This application is in substantial compliance with applicable criteria and standards. This proposal is for the offering of mobile positron emission tomography services.

SHP Policy Statement (PS) Regarding PET

PS-2 Indigent/Charity Care: The applicant states that it will provide a reasonable amount of indigent/charity care.

PS-5 Access to Supplies: According to the applicant, Bethesda will have access to appropriate radio-pharmaceuticals.

PS-6 Services and Medical Specialties Required: The applicant states that the proposed project (GE Discovery ST4 PET/CT unit #63) will function as a component of a comprehensive outpatient diagnostic service through contractual relationships

with Northwest Mississippi Regional Medical Center, which has all of the required diagnostic imaging modalities and capabilities available in close proximity to Bethesda's facility.

The applicant provided a copy of a transfer agreement between Northwest Mississippi Regional Medical Center and Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center for the proposed project.

PS-8 CON Approval: The applicant proposes to provide mobile PET services through the utilization of a mobile PET scanner unit provided by Alliance Imaging, Inc. This equipment vendor is CON approved for PET equipment/services (CON #R-0503). This unit is identified as a GE Discovery ST4 PET/CT unit #63.

PS-13 –Certification

Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center certifies that the mobile equipment identified in Bethesda's proposed CON application to be used to provide PET and/or PET/CT at Bethesda will be the only equipment utilized for the referenced service offered by Bethesda.

SHP Criterion 1 - Need

According to the Certificate of Need criteria and standards for the offering of fixed or mobile positron emission tomography (PET) services, the entity desiring to offer PET services must document that the equipment shall perform a minimum of 1,000 clinical procedures per year and must show the methodology used for the projection.

The proposed mobile PET services will be shared between Bethesda and other health care providers (see table 1 at SHP Criterion 2) on Alliance Imaging's mobile PET/CT services route. The PET system is owned and operated by Alliance Imaging, Incorporated. The applicant proposes to lease, from Alliance Imaging, a General Electric Discover ST 4 PET/CT unit #63 at its facility.

According to the applicant, Alliance Imaging, LLC's mobile PET/CT unit #63 route provided 1,737 PET/CT scans for 2007. These are out of state facilities. Annualized, the route from January-December 2008 will perform 1,061 scans.

SHP Criterion 2 – Utilization of Joint Service Providers

As previously mentioned, the proposed mobile PET services will be shared between Bethesda and other health care providers on Alliance Imaging's mobile PET services route. The PET system is owned and operated by Alliance Imaging, Incorporated. The applicant proposes to lease, from Alliance Imaging, a General Electric Discover ST 4 PET/CT unit at its facility.

The applicant states that the proposed route of Alliance Imaging, LLC will jointly consist of Bethesda Regional Cancer Center, Clarksdale; Delta Cancer Institute,

Greenville; DeSoto Imaging and Diagnostics, LLC, Southaven; and Jeff Anderson Regional Medical Center, Meridian, Mississippi.

The applicant projects 22 PET procedures for the first year, 113 PET procedures for the second year, and 115 PET procedures for the third year of operation for the proposed project.

According to the applicant, Table 1 gives the actual 2007 reported and projected PET/CT scan utilization of each facility:

Table 1
Alliance Imaging, LLC's Actual and Projected Mobile PET/CT Scans

Facilities	#PET/CT Procedures (Mobile) First Year
Jeff Anderson Regional Medical Center	325*
Desoto Imaging and Diagnostics, LLC***	234**
Bethesda Regional Cancer Treatment Center	
Delta Cancer Institute	22**
Maury Regional Medical Center	45**
Total	416**
	1,042
Facilities	#PET/CT Procedures Second Year
Jeff Anderson Regional Medical Center	325*
Desoto Imaging and Diagnostics, LLC***	312**
Bethesda Regional Cancer Treatment Center	
Delta Cancer Institute	113**
Maury Regional Medical Center	220**
Total	572**
	1,542
Facilities	#PET/CT Procedures Third Year
Jeff Anderson Regional Medical Center	325*
Desoto Imaging and Diagnostics, LLC***	390**
Bethesda Regional Cancer Treatment Center	
Delta Cancer Institute	115**
Maury Regional Medical Center	224**
Total	624**
	1,678

*Actual 2007 reported PET/CT utilization

**Projected PET/CT utilization

***This facility's CON application for the establishment and provision of mobile positron emission tomography PET services is pending a Hearing During the Course of Review before the Department.

According to the applicant, the route will serve Jeff Anderson Regional Medical Center, Meridian, one day per week, Desoto Imaging of Southaven one day per week, Maury Regional Medical Center in Columbia, Tennessee two days per week, and Delta Cancer Institute in Greenville and Bethesda Regional Cancer Treatment Center in Clarksdale one day a week each. The applicant

asserts that the referenced equipment route will not interfere on each facility schedules. The applicant states that it will schedule the route as efficiently as possible and assign the five facilities to the route for six different days, Monday through Saturday each week; therefore, the route appears to be reasonable.

SHP Criterion 3 - Assurance

The applicant assures that it will comply with this criterion through its proposed PET/CT services which will be offered in a physical environment that conforms to the federal standards, manufacturer's specifications, and licensing agencies' requirements.

SHP Criterion 4 – Approval from Radiological Health

The applicant affirms that Bethesda will obtain all necessary approvals from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

SHP Criterion 5 – Availability of Equipment

The applicant asserts that Alliance will contractually arrange for the provision of radiopharmaceuticals for Bethesda's PET/CT service through Alliance's existing contracts with PetNet, a national radiopharmaceutical provider. The radiopharmaceutical providers contractually assure quality control of their products and timely supply of required radiopharmaceuticals.

SHP Criterion 6 – Staffing Availability

The applicant asserts that the following staff will be available at Bethesda for the proposed project:

- William R. Richards, MD, the radiation oncologist at Bethesda, will serve as Bethesda's radiation safety officer and authorized user on the radioactive materials license. Dr. William R. Richard's Curriculum Vitae is included in the application.
- Justin L. Boykin and Joy D. Bright will be available to serve as PET technologists at Bethesda. The application contains copies of the license/registration of Justin L. Boykin and Joy D. Bright concerning nuclear medicine technology for the proposed project. The application contains an agreement between Alliance Imaging, LLC (the PET vendor) and USTeleradiology, Atlanta, Georgia for the proposed project.
- Paula Sykes, a staff radiation therapist at Bethesda, will be available for the proposed project. Paula Sykes's resume is included in the application.
- Lana Aguzzi, BSRS, R.T. a simulator and staff radiation therapist at Bethesda

will be available for the proposed project. Lana Aguzzi's resume is included in the application.

SHP Criterion 7 – Medical Emergencies

According to the applicant, in the event of a medical emergency arising within the PET/CT unit, emergency services will be called and the patient subsequently stabilized and transported by EMS personnel to the Northwest Mississippi Regional Medical Center emergency room pursuant to an existing transfer/referral agreement between Bethesda and Northwest Mississippi Regional Medical Center. The application contains a copy of a transfer/referral agreement between Bethesda and Northwest Mississippi Regional Medical Center for the proposed project.

SHP Criterion 8 – Referral System

The applicant affirms that Bethesda will accept appropriate referrals for PET/CT procedures from all local providers, regardless of whether affiliated with Bethesda or its affiliates, and that the patient will be accommodated to the extent possible by extending hours of service, as appropriate, and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

SHP Criterion 9 – Established Protocols

The applicant affirms that protocols will be established to assure that all clinical PET/CT procedures performed are medically necessary and not more appropriately performed by other, less expensive, established modalities.

SHP Criterion 10 – Maintenance of PET Procedures

The applicant states they will maintain and provide to referring physicians or potential referring physicians current listings of appropriate PET/CT procedures and the medical conditions and/or diagnoses related thereto.

SHP Criterion 11 – Maintenance of Required Data

According to the applicant, Bethesda shall maintain the data required by this criterion and shall make same available to the Mississippi State Department of Health upon request.

SHP Criterion 12 – CON Exemption/Approval

Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center is requesting CON authority through the Mississippi State Department of Health to offer mobile PET/CT scanner services. Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center proposes to contract with Alliance Imaging, LLC for mobile PET/CT service. Alliance Imaging has CON approval to control mobile PET scanner

equipment. The CON number is R-0503 (acquisition and establishment of PET scanner equipment/services).

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual*, revised February 23, 2008; addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 2 - Long Range Plan

According to the applicant, the long-range plan of Bethesda includes ultimately delivering a full line of cancer treatment services and modalities, together with necessary ancillary diagnostic imaging and monitoring services, to enable its patients to receive all of their cancer treatment and follow-up at Bethesda without having to travel to remote locations.

GR Criterion 3 - Availability of Alternatives

The applicant considered the following three alternatives:

1. Bethesda considered taking no action, which was determined to be detrimental to Bethesda's patients since most of its patients required a PE/CT scan either to evaluate the best course of treatment and the parameters of treatment of their cancer and/or during the course of their radiotherapy treatment to evaluate the treatment progress/efficacy.
2. The applicant considered buying a PET/CT unit to install at Bethesda Regional Cancer Treatment Center. This alternative was rejected for multiple reasons. One, the capital expenditure required to obtain such equipment would be substantial, particularly when compared to a much more efficient acquisition of access to equipment by mobile/shared services contracting; another was the consideration of the resource duplicative nature of such a purchase.
3. Finally, the applicant considered obtaining mobile shared services by way of an operating lease with a mobile equipment provider which would reduce the financial risk and would substantially reduce the capital expenditure necessary to provide that service locally to Bethesda's patients. Such service arrangements will provide the applicant with flexibility in scheduling the time and volume of PET/CT services to match its patients' PET requirements.

The applicant believes that the provision of PET/CT services for patients of Bethesda through a mobile/shared arrangement benefits the health system by the avoidance of unnecessary duplication of major medical equipment and economic leveraging of major medical equipment service to multiple PET/CT service providers.

GR Criterion 4 - Economic Viability

Based on the applicant's three-year projections, this project will realize a net income of \$37,620; \$193,654; and \$197,081 for the first, second, and third year of operation, respectively.

- a. **Proposed Charge:** The applicant projects charges of \$3,000 per PET procedure for the first three years of operation for the proposed project. The applicant projects costs of \$1,215 per PET procedure for the first year; \$1,211 for the second and third year of operation.
- b. **Projected Levels of Utilization:** Bethesda makes the following projections of PET procedures to be performed during the first three years of operation: 22, 113, and 115, respectively.
- c. **Project's Financial Feasibility Study:** The capital expenditure for this project is \$67,000; therefore, a feasibility study is not required since the capital expenditure does not exceed \$2,000,000.

GR Criterion 5 - Need for the Project

- a. **Access by Population Served:** The applicant asserts that the population currently served by Bethesda will be the population anticipated to be served by the proposed project. Bethesda provides services exclusively to cancer patients. Cancer patients who are receiving treatment generally receive chemotherapy and/or radiation therapy. The facility currently provides radiation therapy services to such cancer patients. The applicant asserts that virtually all of Bethesda's patients (other than bladder and prostate cancer patients) obtain PET scans for cancer staging purposes.

According to the applicant, during the past 12 months, Bethesda's radiation oncologist referred patients for PET scans to third party PET providers 18 times and other physicians are known to have referred Bethesda patients for PET scans as well.

- b. **Relocation of Services:** This application is for the establishment and provision of mobile positron emission tomography services through a contract agreement with Alliance Imaging, LLC of Alabaster, Alabama, an existing provider of mobile PET services.
- c. **Probable Effect on Existing Facilities in the Area:** The applicant believes that there will be no adverse impact to the existing health care system in Mississippi as a result of the proposed project. Because Bethesda is targeting only its existing cancer patients, there will be no adverse impact on other providers of PET services in Mississippi.

- d. **Community Reaction:** The application contains three (3) support letters for the proposed project.

GR Criterion 6 - Access to the Facility or Service

According to the applicant, all residents of General Hospital Service Area 2, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly, will have access to the services of the facility.

The following table shows the projected percentage of gross patient revenue and actual dollar amount of health care provided to medically indigent patients for years one and two for the proposed project:

Projected Year	Total Dollar Amount of Gross Patient Revenue
1	\$58,000 (1.35%)
2	\$59,160 (1.35%)

According to Bethesda, the facility provided 2.79 percent of gross patient revenue to medically indigent patients for 2008, annualized.

GR Criterion 7 - Information Requirement

The applicant states that it will record and maintain the requested information required by this criterion and make it available to the Mississippi State Department of Health within 15 days of request.

GR Criterion 8 - Relationship to Existing Health Care System

Bethesda Regional Cancer Treatment Center is located in General Hospital Service Area 2. According to the **FY 2009 State Health Plan**, in FY 2007, GHSA 2 had a total of two mobile PET provider locations, with a total of 453 PET procedures. The applicant believes that the project will not have an adverse effect on the existing health care system.

Staff concludes that this project should have no adverse affect on existing providers in GHSA 2.

GR Criterion 9 - Availability of Resources

The applicant states that Alliance Imaging, LLC will provide the appropriate trained PET technologists. William R. Richards, MD, the radiation oncologist at Bethesda, will serve as Bethesda's radiation safety officer and authorized user on the radioactive materials license. Dr. William R. Richards' Curriculum Vitae is included

in the application. As previously mentioned, Bethesda will have other qualified staff available for the proposed project.

GR Criterion 16 - Quality of Care

Bethesda Regional Cancer Treatment Center is an established provider of therapeutic radiation services and will be a new provider of PET services. The applicant asserts that Bethesda has a substantial history of quality radiation therapy care and is committed to continuing that level of care to its patients. According to Bethesda, the proposed project will allow PET/CT services at Bethesda rather than referring their patients to other facilities for PET and/or PET/CT scans.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

	Cost Item	Project Cost	Percent
a.	Construction – New	0	0
b.	Renovation	0	0
c.	Capital Improvements	\$ 27,500	41.04%
d.	Fixed Equipment	0	0
e.	Non-Fixed Equipment	0	0
f.	Land	0	0
g.	Site Preparation	\$ 1,000	1.49%
h.	Fees (Architectural, Consultant, etc.)	\$ 10,000	14.93%
i.	Contingency Reserve	\$ 20,000	29.86%
j.	Capitalized Interest	0	0
k.	Other	\$ 8,500	12.68%
l.	Total Proposed Capital Expenditure	\$ 67,000	100%

The above estimated capital expenditure is proposed to create the concrete pad and electrical connections (capital improvement cost) necessary to accommodate the mobile PET/CT unit/services at Bethesda.

B. Method of Financing

The applicant proposes to finance the proposed capital expenditure from accumulated cash reserves.

C. Effect on Operating Cost

Bethesda Regional Cancer Treatment Center PET Service projects the following expenses, revenues, and utilization for the first three years of operation:

	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient	-0-	-0-	-0-
Outpatient	66,000	339,000	345,000
Total Gross Patient Revenue	<u>\$66,000</u>	<u>\$ 339,000</u>	<u>\$ 345,000</u>
Charity Care	(\$1,650)	(\$8,475)	(\$8,625)
Deductions	-0-	-0-	-0-
Total Deductions	<u>(\$1,650)</u>	<u>(\$8,475)</u>	<u>(\$8,625)</u>
Net Patient Revenue	<u>\$64,350</u>	<u>\$330,525</u>	<u>\$336,375</u>
Other Operating Revenue	-0-	-0-	-0-
Total Operating Revenue	<u>\$64,350</u>	<u>\$330,525</u>	<u>\$336,375</u>
Expenses			
Salaries	\$ 2,090	\$10,735	10,925
Supplies	440	2,260	2,300
Services	3,300	16,526	16,819
Lease	20,900	107,350	109,250
Other	-0-	-0-	-0-
Total Expenses	<u>\$26,730</u>	<u>\$136,871</u>	<u>139,294</u>
Net Income (Loss)	<u>\$37,620</u>	<u>\$193,654</u>	<u>\$197,081</u>
Utilization			
Inpatient Day	-0-	-0-	-0-
Outpatient Day	250	250	250
Procedures	22	113	115
Charge Per Procedure	\$3,000	\$3,000	\$3,000
Cost Per Procedure	\$1,215	\$1,211	\$1,211
Charge Per Outpatient Day	-0-	-0-	-0-
Charge Per Inpatient Day	-0-	-0-	-0-
Cost Per Outpatient Day	-0-	-0-	-0-
Cost Per Inpatient Day	-0-	-0-	-0-

D. Cost to Medicaid/Medicare

Patient Mix by Type Payer	Utilization Percentage	First Year Expenses Revenue
Medicaid	-0-	-0-
Medicare	-0-	-0-
Other	100	\$60,000
Total	<u>100</u>	<u>\$66,000</u>

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. However, no comments were received.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the offering of mobile positron emission tomography (PET) services as contained in the *FY 2009 State Health Plan*; the *Certificate of Need Review Manual*, revised February 23, 2008; and all adopted rules, procedures and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Alliance Oncology, LLC d/b/a Bethesda Regional Cancer Treatment Center for the establishment and provision of mobile positron emission tomography services.